DOCKET NO.: JJTP-0027 / TPI5013USPCT6 PATENT

Application No.: 10/541,216

Office Action Dated: January 8, 2010

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1-45. (Canceled)

46. (*Currently amended*) A pharmaceutical composition comprising: (a) a salt form of an active pharmaceutical ingredient (API) having an aqueous solubility less than about 10 mg/mL in gastric fluid conditions; (b) a precipitation retardant; and (c) an optional enhancer; wherein the composition retards crystallization or precipitation of the API for at least 5 minutes in gastric fluid conditions, wherein the pharmaceutical composition is formulated in a form suitable for oral administration.

- 47. (Previously presented) The pharmaceutical composition according to claim 46, wherein the precipitation retardant is a surfactant.
- 48. (Previously presented) The pharmaceutical composition according to claim 46, wherein the precipitation retardant is a surfactant and exhibits an interfacial tension of less than about 10 dyne/cm or a surface tension of less than about 42 dyne/cm.
- 49. (Previously presented) The pharmaceutical composition according to claim 46, wherein the precipitation retardant is a poloxamer.
- 50. (Original) The pharmaceutical composition according to claim 46, wherein the composition comprises an enhancer.
- 51. (Previously presented) The pharmaceutical composition according to claim 46, wherein the composition comprises HPC or HPMC as an enhancer.
- 52. (Previously presented) The pharmaceutical composition according to claim 46, wherein crystallization or precipitation is retarded for at least 20 minutes.

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53. (Previously presented) The pharmaceutical composition according to claim 46,

wherein crystallization or precipitation is retarded for at least 40 minutes.

54. (Previously presented) The pharmaceutical composition according to claim 46,

wherein crystallization or precipitation is retarded for at least 60 minutes.

55. (Previously presented) The pharmaceutical composition according to claim 46,

wherein the API is a sulfonamide.

56. (Previously presented) The pharmaceutical composition according to claim 46,

wherein the API is a benzene sulfonamide.

57. (Previously presented) The pharmaceutical composition according to claim 46,

wherein the API is celecoxib, deracoxib, valdecoxib, rofecoxib or eturicoxib.

58. (Previously presented) The pharmaceutical composition according to claim 46,

wherein the salt form of the API is an alkali metal or alkaline earth metal salt.

59. (Previously presented) The pharmaceutical composition according to claim 46,

wherein the salt form of the API is a sodium, potassium, lithium, or calcium salt.

60. (Previously presented) The pharmaceutical composition according to claim 46,

wherein the bioavailability of the composition orally administered is at least 70%.

61. (Previously presented) The pharmaceutical composition according to claim 46,

wherein the bioavailability of the composition orally administered is as least 80%.

62. (Previously presented) The pharmaceutical composition according to claim 46,

wherein the bioavailability of the composition orally administered is as least 90%.

63. (Previously presented) The pharmaceutical composition according to claim 46,

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wherein the C_{max} is at least 2 fold greater than a neutral form in vivo or in an in vitro dissolution assay.

64. (Previously presented) The pharmaceutical composition according to claim 46, wherein the C_{max} is at least 4 fold greater than a neutral form in vivo or in an in vitro dissolution assay.

- 65. (Previously presented) The pharmaceutical composition according to claim 46, wherein the C_{max} is at least 10 fold greater than a neutral form in vivo or in an in vitro dissolution assay.
- 66. (Previously presented) The pharmaceutical composition according to claim 46, wherein the bioavailability of the composition is at least 50% greater than a neutral form.
- 67. (Original) The pharmaceutical composition according to claim 46, wherein the bioavailability of the composition is at least 2 fold that of a neutral form.
- 68. (Previously presented) The pharmaceutical composition according to claim 46, wherein the bioavailability of the composition is at least 5 fold that of a neutral form.
- 69. (Withdrawn) A process for producing a pharmaceutical composition for delivering a supersaturated concentration of a drug having an aqueous solubility less than about 10 mg/mL in gastric fluid conditions, which process comprises intimately mixing together components: (a) a salt form of an API having an aqueous solubility less than about 10 mg/mL in gastric fluid conditions; (b) a precipitation retardant; and (c) an optional enhancer.
- 70. (Withdrawn) The process for producing a pharmaceutical composition according to claim 69, wherein the API is a sulfonamide.
- 71. (Withdrawn) The process for producing a pharmaceutical composition according to claim 69, wherein the API is a benzene sulfonamide.

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72. (Withdrawn) The process for producing a pharmaceutical composition according to claim 69, wherein the API is celecoxib, deracoxib, valdecoxib, rofecoxib or eturicoxib.

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73. (Withdrawn) The process for producing a pharmaceutical composition according to claim 69, wherein the salt form of the API is an alkali metal or alkaline earth metal salt.

74. (Withdrawn) The process for producing a pharmaceutical composition according to claim 69, wherein the salt form of the API is a sodium, potassium, lithium, or calcium salt.